

REMARKS

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

Entry of the amendments is proper under 37 CFR §1.116, because the amendments place the application in condition for allowance and do not raise any new issue requiring further search and/or consideration. The amendments are necessary and were not earlier presented, because they are made in response to arguments raised in the final rejection. Entry of the amendments is thus respectfully requested.

Claims 1, 2, 5, 8 and 10 are pending in this application.

Claim 1 has been amended to recite “the polymerization proceeds in the presence of a non-volatile metallic catalyst selected from the group consisting of oxides, chlorides, carboxylates and alkoxides of tin (Sn), titanium (Ti), aluminum (Al), antimony (Sb), zirconium (Zr) and zinc (Zn)”. Support for this amendment can be found in paragraph [0020] of the specification.

In addition, the final heat-treatment step of claim 1 has been amended to recite “then contacting the pelletized aliphatic polyester containing the thermal stabilizer with a flowing heated dry gas under normal pressure while retaining the pelletized aliphatic polyester in its solid state, thereby entraining the residual cyclic ester with the gas and reducing the residual cyclic ester content down to below 0.2 wt.%”. Support for this amendment can be found in paragraph [0030] of the specification.

I. Claim Rejection Under 35 U.S.C. § 103

The Examiner has maintained the rejection of claims 1, 2, 5, 8 and 10 under 35 U.S.C. § 103(a) as being unpatentable over DeProspero (US 3,565,869) combined with Yamane et al. (US 2003/0125431) and further in view of Terado et al. (U.S. 6,528,617). As applied to the amended claims, Applicants respectfully traverse the rejection.

In the previous response filed July 6, 2011, Applicants traversed the rejection based upon the following three arguments:

(1) First, the process of DeProspero already achieves a residual glycolide content of less than 0.2% (see col. 3, lines 34-44), and therefore provides no reason or motivation for a person of ordinary skill in the art to add an additional heat treatment to the PGA product in order to obtain a residual glycolide content of less than 0.2 %.

(2) Second, paragraph [0021] of Yamane et al. teaches the application of heat history to PGA within a temperature range higher than the melting point T_m , but not higher than $(T_m+100^{\circ}\text{C})$. As a result, the reference teaches the heat treatment to the PGA is in a “molten state”, rather than a “pelletized solid state”, as in the claimed invention.

(3) Third, Terado et al. states “However, in the aliphatic polyester of the present invention, the content of lactide is 1000 ppm or less [i.e., less than 0.1%] at the time before the heat treatment, and therefore the improvement of thermal stability resulted in by the heat treatment according to the present invention is not achieved by removal of lactide” (see col. 2, lines 39-44). In fact, however, the reference further teaches a post-treatment of an aliphatic polyester obtained after solid phase polymerization in the presence of a volatile catalyst, such as an organic sulfonic acid, by a solid-state heat treatment under a flowing gas to provide improved thermal stability by removal of the volatile organic catalyst (see col. 3, lines 44-57, and Example 1). Example 1 of the reference demonstrates the reduction of an organic sulfonic acid content from 180 ppm to 90 ppm for providing an increase in retentiveness of molecular weight in pressing of from 72% to 93% (see Production Example 1 at col. 12, lines 28-30, and Example 1 at col. 14, lines 36-38).

Therefore, neither DeProspero nor Terado et al. provide any reason or motivation to one of ordinary skill in the art to apply the heat treatment of Terado et al. to the PGA of DeProspero, which already has a low glycolide content of less than 0.2%.

In response to the arguments above, the Examiner has asserted that DeProspero does not exclude an additional heat treatment of its product having a reduced residual monomer content, as taught by Terado et al. (see item 2.2 on pages 3-4 of the Office Action).

Applicants acknowledge that this argument may be partly tenable. However, claim 1 has been amended to recite “then contacting the pelletized aliphatic polyester **containing the thermal stabilizer** with a flowing heated dry gas under normal pressure **while retaining the pelletized aliphatic polyester in its solid state**, thereby entraining the residual cyclic ester with the gas and reducing the residual cyclic ester content down to below 0.2 wt.%”.

Thus, the step of the claimed process that is not disclosed by DeProspero is the final heat treatment for further reduction of a residual monomer of the pelletized polyglycolic acid (1) containing a thermal stabilizer, (2) containing a non-volatile organic catalyst, (3) a flowing heated dry gas, (4) under normal pressure, and (5) while retaining the solid state of the pelletized

poly glycolic acid.

Yamane et al.

Yamane et al. states, "When the method in which heat history is applied to polyglycolic acid and the method in which the heat stabilizer is added to crystalline polyglycolic acid is used in combination, a polyglycolic acid composition modified in thermal properties and moreover improved in melt stability can be provided" (see paragraph [0021]). Thus, the reference teaches melt-kneading of a polyglycolic acid with a thermal stabilizer in the application of heat history in order to modify the thermal properties and **improve the melt stability** of a polyglycolic acid composition. This teaching provides no reason or motivation for features (1) adding a thermal stabilizer to polyglycolic acid to be heat-treated, and (5) retaining **the solid state** of the pelletized poly glycolic acid for further removal the residual monomer, as in the claimed process.

Terado et al.

Terado et al. teach a heat treatment of an aliphatic polyester after a solid-phase polymerization (5) in a solid state by (3) contact with a flowing heated dry gas, (4) under normal pressure. However, the heat treatment is not for the further removal of a residual monomer content, which is already 1000 ppm (=0.1%) or less, before the heat treatment (see col. 2, lines 38-44). Rather, the heat treatment is for the removal of a residual volatile organic catalyst used in the solid-phase polymerization (see col. 3, lines 44-57, as discussed above).

Accordingly, Terado et al. do not provide any reason or motivation to apply its heat treatment for the further removal of a residual monomer from an aliphatic polyester after a solid-phase polymerization is performed by using (2) a non-volatile organic catalyst, as in the claimed process, to DeProspero.

Therefore, one of ordinary skill in the art would not have been motivated to apply the heat treatment of Terado et al. for the further reduction of a residual monomer characterized by features (1)-(5) of the claimed heat treatment process to the product polyglycolic acid of DeProspero in view of Yamane et al. Accordingly, one skilled in the art would not have had any reason to combine the teachings of the references to arrive at the presently claimed process.

Therefore, claim 1 would not have been obvious over the references.

Claims 2, 5, 8 and 10 depend from claim 1, and thus also would not have been obvious over the references.

Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

II. Conclusion

For these reasons, Applicants take the position that the presently claimed invention is clearly patentable over the applied references.

Therefore, in view of the foregoing amendments and remarks, it is submitted that the rejection set forth by the Examiner has been overcome, and that the application is in condition for allowance. Such allowance is solicited.

Respectfully submitted,

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October 19, 2011